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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/691,405	10/17/2000	Steven R. Binder	2558B-063700US	3942

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EXAMINER	
ALLEN, MARIANNE P	
ART UNIT	**PAPER NUMBER**
1631	6

DATE MAILED: 01/29/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/691,405	BINDER ET AL.	
	Examiner	Art Unit	
	Marianne P. Allen	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 November 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10 and 12-16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10 and 12-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *4, 5* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claim 11 has been cancelled.

Applicant's arguments filed 11/1/02 have been fully considered but they are not persuasive.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The rejection of claims 1, 3, and 11-14 under 35 U.S.C. 102(b) as being anticipated by Grus et al. (*Electrophoresis*, ***18***:1120-1125, 1997) is withdrawn in view of the amendments to the claims.

Claim Rejections - 35 USC § 112

Claims 1-10 and 12-16 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

This rejection is maintained essentially for reasons of record. Applicant's arguments are not persuasive.

Applicant's arguments that applying pattern recognition means would be within the skill of the art is not persuasive. Applicant admits that the invention is applying known pattern recognition means to solve a new problem. This is not a situation where new data is input into known programs for solving the problem. That is, applicant is not using known software to solve a known problem in a conventional manner where one practicing the invention need only supply the data to be analyzed. Applicant admits that the known statistical techniques will need to be

adapted to solve this particular problem. However, the specification has not exemplified any method for identification within the claims nor provided guidance on the how to adapt the known statistical techniques for solving the problem of identifying systemic autoimmune disease in a subject. One of ordinary skill in the art would be required to make independent decisions and judgments on how to apply the statistical techniques, what parameters to use or change, assumptions to make, and so forth. Any model developed must be tested and validated. This is not considered to be routine experimentation. This is an invention to experiment and to develop applicant's claimed method.

Applicant is reminded that claims 1-6, 9-10, and 12-16 do not specify the antibodies to be compared. The specification does not exemplify or identify any known library of reference data sets where "each data set [is] obtained from a biological sample of a reference subject known to have a systematic autoimmune disease of known identity." In particular, at least claims 9 and 10 require libraries of significant size (up to 2000 or 10000 biological samples) that have not been developed and thus are not available to one of ordinary skill in the art to practice the invention. At least Claim 5 encompasses a test data of up to 100 autoantibodies and the specification specifically identifies less than half of that number.

In *In re Wands* (8 USPQ2d 1400 (CAFC 1988)) the CAFC considered the issue of enablement in molecular biology. The CAFC summarized eight factors to be considered in a determination of "undue experimentation." These factors include: (a) the quantity of experimentation necessary; (b) the amount of direction or guidance presented; (c) the presence or absence of working examples; (d) the nature of the invention; (e) the state of the prior art; (f) the relative skill of those in the art; (g) the predictability of the art; and (h) the breadth of the claims.

In the instant application, a great deal of experimentation would be required that is not routine. The specification provides no direction or guidance on how to adapt known statistical pattern recognition means to solve their particular problem. There are no working examples. Computational methods of diagnosis are quite complicated such that even though the skill of those in the art is high, such inventions are difficult to develop and validate. Note that none of the prior art identified by applicant concerns diagnosis of any disease using any antibody profiles and pattern recognition means. The prior art to Grus et al. demonstrates the amount of effort required to develop such methods and all of the different decisions that must be made when determining how to solve a particular problem. The specification provides none of this information or guidance for any aspect of the invention. Again, the specification does not associate any antigen (or autoantibody) with any particular disease with respect to presence (or absence) and amounts as implied by the claims. That is, they do not exemplify any embodiment of tthe claimed method. Nor does the specification disclose how discrimination between different autoimmune diseases, particularly with those that involve overlapping autoantibodies, is to be implemented. (See Thompson et al., 1993.) Finally, the breadth of the claims is broad for many aspects of the claims from the pattern recognition means, to the number and type of autoantibodies in the test data and library of reference data sets, to the diseases to be identified.

Claims 1-10 and 12-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It remains unclear what symptoms the test subject of must possess to meet the limitation of being "suspected of suffering from an otherwise unidentified systemic autoimmune disease" selected from the named group. While applicant points to documents listed on the IDS, the specification does not provide the metes and bounds of what is intended. One of ordinary skill in the art is not reasonably apprised of which test subjects are embraced by the claims.

As amended, claim 2 remains confusing. It still requires foreknowledge that the test subject is suffering from two otherwise unidentified autoimmune diseases.

Claim 3 is confusing in referring to the listed statistical analysis techniques as pattern recognition means. Again, page 5, lines 6-13, of the specification do not identify these statistical techniques as pattern recognition means.

Claim Rejections - 35 USC § 102

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marianne P. Allen whose telephone number is 703-308-0666. The examiner can normally be reached on Monday-Friday, 7:00 am - 1:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 703-308-4028. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Marianne P. Allen
Primary Examiner
Art Unit 1631

mpa
January 27, 2003